13.8 Electromagnetic Compatibility

The Ottava system has been tested and found to be in compliance with IEC 60601-1-2:2020, Edition 4.1, International standard for Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

The Ottava system is classified as Industrial, Scientific, and Medical or (ISM) device to be used specifically in an operating room environment. The performance of the system is unaffected when exposed to the electromagnetic environmental conditions as described in the IEC 60601-1-2 EMC standard. There is no degradation of functional performance and therefore no risks to the patient or other devices due to Electromagnetic Interference (EMI) when used within the electromagnetic environment as specified in Tables **13.5** to **13.14** within the following sections.

All equipment within the operating room environment, including the Ottava system and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), which may affect the function of these devices. Such effects are prevented by use of equipment with EMI characteristics proven below recognized limits, as identified in the following tables.

WARNING: The use of instruments, cables, or accessories other than those specified or provided by Johnson & Johnson as replacement parts for the System could result in increased electromagnetic emissions or decreased electromagnetic immunity of the System and result in improper operation or degraded performance and compromised EMC Compliance.

WARNING: Symptoms of interference could include repeated faults, unintentional movement of Surgical Arms, loss of connection to the Endoscope or Instruments, or frozen video or loss of video. If the System does not properly function and interference from other equipment is suspected, discontinue use of the System and contact Johnson & Johnson.

WARNING: The System should not be used adjacent to or stacked with other equipment as this could result in improper operation. If such a configuration is required, observe the System to verify normal operation.

WARNING: Use portable RF communications equipment, including peripheral equipment, such as antenna cables and external antennas, no closer than 30 cm (12 inches) to any part of the System, including cables specified by the manufacturer and result in degraded performance of the System.

WARNING: The System contains and may be used with electrosurgical devices such as ESUs. System use in the presence of MRI, diathermy devices, or electromagnetic security systems has not been tested. The System should not be used in the vicinity of these devices to prevent potential patient or user harm.

WARNING: The wireless coexistence testing conducted by Johnson & Johnson does not cover System use in the presence of MRI, or diathermy devices or machines.

NOTE: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

13.9 FCC Compliance

This ISM equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to 47 CFR Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference to and from the equipment when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy that may cause harmful interference to radio communications when not installed and used in accordance with the user manual.

This equipment requires reliable grounding for reduced radiated radio frequency energy and electromagnetic interference. This equipment requires “Hospital Grade” power receptacles and utilizes “Hospital Grade” power plugs to achieve reliable grounding.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications made to this device that are not expressly approved by Auris Health, Inc. could void the user's authority to operate the equipment.

13.10 Functional Performance Criteria

The functional performance of the system during EMC testing was defined in the following.

- The System displays a sufficiently illuminated real-time clinically acceptable image of the surgical site. If the displayed image is not live, such as when displaying a recorded image or in the event of system malfunction, it is apparent to the user that the displayed image is not a live image. (Temporary image degradation subtle image noise, speckling, transient flashing is acceptable.)
- The Robotic instrument tip, shaft and instrument arm move only in response to motions of the matched Haptic Interface Device (HID) with no uncontrolled or unexpected motions.
- The Integrated Table moves as commanded by the operator but does not move during Teleoperation and/or simulated Robotic Surgery modes.
- HF Surgical CUT and/or COAG energy activation only when commanded.
- System continuously recognizes attached instruments and tools.
- Critical faults during immunity testing with “Head Present” will immediately stop the robotic operation of the system and prevent the user from continuing to perform teleoperation. Critical faults are non-recoverable faults that require system power cycling to recover (unless specifically allowed by the medical standard IEC 60601-1-2).

13.11 Electromagnetic Emissions and Immunity Specifications

The System includes three sub-systems: the Tower for central control, Physician Console for control input and the Integrated Table for patient bed and robotic Surgical Arms. All subsystem interfaces are provided through electrical and optical fiber cables. Software is also a component of this system.

The following tables contain Manufacturer's electromagnetic emissions and immunity declaration required by IEC 60601-1-2:2020.

Table 13-5. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified. The customer or user of the System should make sure it is used in such an environment.

<table>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic Environment Guidance</th></tr>
<tr><td rowspan="2">RF Emissions
CISPR 11</td><td>Group 1[a]
Class A[c]</td><td>The Integrated Table and Physician Console uses RF energy only for its internal function. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Group 2[b]
Class A[c]</td><td>The Tower used with the Ethicon Megadyne™ ESU must emit electromagnetic energy in order to perform its intended function.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1[a]
Group 2[b]
Class A[c]</td><td rowspan="3">The System is suitable for use in all establishments other than domestic, and may be used connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Warning: This equipment/system is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the System or shielding the location.
Note: High-frequency (HF) surgical equipment shall meet the limits specified for group 1, class A equipment, in stand-by mode of operation. For high-frequency (HF) surgical equipment operating at frequencies outside designated ISM bands, these limits also apply at the operating frequency and inside the designated frequency bands. The related measurements shall be performed in a test arrangement in accordance with IEC 60601-2-2.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A[c]</td></tr>
<tr><td>Voltage Fluctuations / Flicker Emissions IEC 61000-3-3</td><td>Not Required for 120V/60Hz</td></tr>
</table>

a. Group 1 Equipment contains all ISM equipment in which there is intentionally generated and/or used conductivity-coupled radiofrequency (RF) energy that is necessary for the internal functioning of the equipment itself.

b. Group 2 Equipment contains all ISM equipment in which radiofrequency (RF) energy, in the frequency range 9 kHz to 400 GHz, is intentionally generated and used or only used locally, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material, for inspection/analysis purposes, or for transfer of electromagnetic energy.

c. Class A equipment is ISM equipment suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes. ISM equipment is intended for use in an industrial, scientific, or medical environment.

Table 13.6. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The System is intended for use in the electromagnetic environment specified. The customer or the user of the System should assure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact discharge: ± 8 kV Air discharge: ± 2, 4, 8, 15 kV Class 4[d]	± 8 kV Contact Discharges ± 15 kV Air Discharges	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV AC Mains ± 1 kV I/O Lines 5/50 100 kHz Bursts PRF	± 2 kV AC Mains Lines ± 1 kV Input/output Lines	Mains power quality should be that of a typical commercial or hospital environment. Sharing Mains Power lines with large motors and/or noisy equipment must be avoided.
AC Power Surges IEC 61000-4-5	±.5, 1 kV Line to Line ± .5, 1, 2kV L & N to P.E. 1.2us rise / 50us decay 5 Bursts / 20 sec Delay 0, 90 and 270 Degrees	± 1 kV Differential Mode ± 2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (4th Ed.) Class 4[e]	30 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	10% drop for 0.5 cycle at 8 Angles 0 100% drop for 1 period 30% dip in 30 periods 100% drop in 5 seconds	100% drop UT for 0.5 cycle at eight 45º Phase Angles 100% drop UT for 1 period 30% dip UT in 30 periods 100% drop UT in 5 seconds [f]	Mains power quality should be that of a typical commercial or hospital environment. The OTTAVA Integrated Table includes an uninterruptible power supply.

d. Class 4 immunity environment with humidity as low as 10%, not antistatic and uses synthetic material.

e. Class 4 immunity environment is defined as a typical industrial environment. The environment is characterized by the following attributes:

- Short branch power lines as busbars, etc.
- High power electrical equipment that may give rise to leakage fluxes
- Ground conductors of protection system
- M.V. circuits and H.V. busbars at relative distance (a few tens of meters) from equipment concerned.

f. UT is the AC mains voltage before application of the test level. The OTTAVA Integrated Table provides emergency backup power to allow for a safety power down of the system during a loss of power condition. The available backup time is clearly displayed for the operator.

Table 13.7. Guidance and Manufacturer's Declaration – Electromagnetic RF Immunity

The System is intended for use in the electromagnetic environment specified. The customer or the user of the System should assure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF EM Fields IEC 61000-4-3	3 V/m for 80 MHz to 2.7 GHz at 1KHz modulation. Class 2 [g]	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$, (150 KHz to 80 MHz, IEC 61000-4-6) $d = 1.2\sqrt{P}$, (80 MHz to 800 MHz, IEC 61000-4-3) $d = 2.3, \sqrt{P}$, (800 MHz to 2,7 GHz, IEC 61000-4-3) where, *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [h] should be less than the compliance level in each frequency range. [i] Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	380 MHz to 6.0 GHz in V/m per 4th Edition levels (See Table 13.9 for specific frequency and energy levels.	9V/m to 28V/m	
Conducted Disturbances Induced by RF Fields IEC 61000-4-6	3 V_{RMS} 0,15 MHz – 80 MHz Class 2 [g] 6 V_{RMS} in ISM bands between 0,15 MHz and 80 MHz	3 V_{RMS} 6 V_{RMS} in ISM bands	
Proximity Magnetic Fields tested per IEC 61000-4-39	30 kHz: CW Modulation 134.2 kHz: 50% Pulse Modulation 2.1 kHz 13.56 MHz: 50% Pulse Modulation 50 kHz	N/A for ISM 65 A/m 7.5 A/m	The magnetic field is applied to those surfaces of the enclosure or attached accessories that are accessible during intended use.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

g. Class 2 immunity environment with Low power portable transceivers (typically less than 1 W rating) are in use, but with restrictions on use in close proximity to the system.

h. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

i. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than ~~6~~ 3 V/m.

Table 13.8. Recommended separation distances between portable and mobile RF communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Radiated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 13.9. Guidance and Manufacturer's Declaration – Proximity Fields from RF Wireless Communications Immunity

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

13.12 Wireless Communication

The Ottava Integrated Table contains an RFID 13.56 MHz Near Field Communication (NFC) device within each of the four Robot ARM Tool Drivers. These RFID modules are used to identify the instruments and tools attached to each Tool Driver. This custom RFID modular design was tested and issued the following intentional radiator modular licensing for North America:

FCC ID: 2BFPV-TDNFCOTT and IC: 32307-TDNFCOTT

Table 13.10 Tool Drive RFID Technical Specifications

Technical Name	Specification
Equipment name	Tool Drive RFID
Antenna type	Integrated Antenna on PCB
Main function	Tool Detection and Data transfer
Modulation mode	ASK
Frequency range	13.56 MHz
Frequency tolerance	≤100 ppm
Transmit Power	0.000441 mW
Working temperature	+10ºC to +24ºC

The Ottava Integrated Table contains four 125 KHz NFC devices used to identify patient head and foot support accessories attached to the patient support system. This custom RFID modular design was tested and issued the following intentional radiator modular licensing for North America:

FCC ID: 2BFPV-TBLNFCOTT and IC: 32307-TBLNFCOTT

Table 13.11 Table NFC Technical Specifications

Technical Name	Specification
Equipment name	Table NFC, Version Alpha 4
Antenna type	Discrete Coil Inductors
Main function	Accessory Detection and Data transfer
Modulation mode	PSK, FSK
Frequency range	125 KHz
Frequency tolerance	≤100 ppm
Transmit Power	0.000025 mW
Working temperature	+10ºC to +24ºC

NOTE: The Ottava System intentional use of wireless communication may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Tool Drive RFID Label:

FCC ID: 2BFPV-TDNFCOTT
IC: 32307-TDNFCOTT
HVIN: Tool Drive RFID

Table Accessory RFID Label:

FCC ID: 2BFPV-TBLNFCOTT
IC: 32307-TBLNFCOTT
HVIN: Table NFC, Version Alpha 4

Integrated Table Subsystem Label:

CONTAINS:

FCC ID: 2BFPV-TDNFCOTT FCC ID: 2BFPV-TBLNFCOTT
IC: 32307-TDNFCOTT IC: 32307-TBLNFCOTT

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

13.13 Wireless Coexistence

Wireless Coexistence with other device that transmit RF energy can impact the reliability of the Ottava system RFID communication. Coexistence testing was performed using wireless devices typically found in an operating room environment.

Wireless Coexistence tests were performed in accordance to test methods in ANSI C63.27-2021, American National Standard for Evaluation of Wireless Coexistence following Annex A.2 for Bluetooth Low Energy, Tier 3 and following the guidance in AAMI TIR69:2017/(R)2020.

The unintended signal parameters (frequency, transmission power, channel utilization):

- IEEE 802.11n frequency: Single-channel testing shall be performed using an IEEE 802.11n, 20 MHz bandwidth signal, centered at 2437 MHz (Wi-Fi Channel 6)
- IEEE 802.11n signal amplitude: The signal amplitude of the unintended IEEE 802.11n signal shall be 20 dBm total radiated power in the radiated setup or 20 dBm at the EUT in the conducted test setup.
- IEEE 802.11n channel utilization: The unintended IEEE 802.11n signal shall operate at 64 QAM
- NFC – 125 kHz Wireless Output: 49.01 dBuV/m @ 1m
- Device: iCopy X100
  RFID – 13.56 MHz Wireless Output: 30.48 dBuV/m @ 1m
  Device: iCopy X100
- WPT – 0.11-0.205 MHz
  Wireless Output: 10 Watts
  Device: Tripp Lite U280-Q02FL-BK
- TRC Wireless Charger – 120 KHz
  Wireless Output: 14.4 Watts
  Device: 1009.24A0/B0/C0